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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,916	07/20/2005	Patrick Colin Hickey	RGC-LUX-PI	9549
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OSTRAGER CHONG FLAHERTY & BROITMAN PC 570 LEXINGTON AVENUE FLOOR 17 NEW YORK, NY 10022-6894			EXAMINER LEE, SHUN K	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,916	Applicant(s) HICKEY, PATRICK COLIN	
	Examiner Shun Lee	Art Unit 2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007 and 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of.
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 and 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It should be noted that a claim may be rendered indefinite by reference to an object that is variable (MPEP § 2173.05(b)). Thus a limitation in a claim to a luminescent device that recited "wherein the device is sized and shaped to be housed in a sample holder" is indefinite because the relationship of parts was not based on any known standard for sizing a luminescent device, but on the dimensions of an unspecified sample holder.

Claim Objections

3. Claims 8, 15, 18, and 20 are objected to because of the following informalities:

(a) in claim 8, "the outer casing" on line 2 (there is insufficient antecedent basis for this limitation in the claim) should probably be --an outer casing--;

(b) in claim 15, "comprising three or more devices, each having a light output of a distinct intensity to the other devices of said kit" on lines 1-2 should probably be --said two or more luminescent devices is three or more devices--;

(c) in claim 18, "," on line 1 should probably be --:--; and

(d) in claim 20, "apparatus" on line 4 should probably be --sample holder--.

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Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 8, and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kessler *et al.* (DE 38 16 489 A1) in so far as understood.

In regard to claims 1 and 10, Kessler *et al.* disclose (Fig. 1) a luminescent device comprising a gaseous tritium light source (GTLS 100) which provides a light output of pre-determinable intensity (see EPO automated translation of abstract), wherein the device is sized and shaped (e.g., a 3 mm diameter cylinder with a height of 15 mm; see EPO automated translation of column 2, lines 60-61) to be housed in a sample holder of light measuring apparatus. Alternatively, it would have been obvious to one having ordinary skill in the art at the time of the invention that the luminescent device of

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Kessler *et al.* is of a size and shape that allows the luminescent device to be housed in a sample holder of light measuring apparatus.

It should be noted that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" (*Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)) if the prior art apparatus teaches all the structural limitations of the claim (MPEP § 2114).

Thus, "light measuring apparatus" and "said apparatus is selected from the group consisting of a luminometer, a fluorometer, a spectrophotometer, a scintillation counter, a photomultiplier, an avalanche photodiode or a CCD camera" were not given any patentable weight since the light measuring apparatus does not appear to impose any additional structural limitations on the claimed luminescent device. Therefore applicant is advised that should claim 1 be found allowable, claim 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In regard to claim 3 which is dependent on claim 1, Kessler *et al.* also disclose (Fig. 2) that the GTLS (100) is located with an outer casing (9b) that inherently have at least one optically transparent or translucent portion to allow for the transmission of light from the GTLS (100).

In regard to claim 8 which is dependent on claim 1, Kessler *et al.* also disclose (Figs. 1 and 2) that the GTLS (100) is held within a housing (101), the housing (101) being located in the outer casing (9b).

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of MacHutchin *et al.* (US 2,953,684).

In regard to claim 2 which is dependent on claim 1, the luminescent device of Kessler *et al.* lacks an explicit description that the GTLS comprises 10 to 20 mCi of tritium. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, lines 3-11) that in one embodiment the GTLS have a radiant flux of approximately 15 μlm to 3.5 mlm and that the radiant flux can be adjusted by the tritium gas pressure for a given luminescent device configuration. Since Kessler *et al.* do not disclose and/or require a specific tritium gas pressure, one having ordinary skill in the art at the time of the invention would reasonably interpret the unspecified tritium gas pressure of Kessler *et al.* as a result effective variable that is to be adjusted so as to obtain a desired radiant flux. Further, MacHutchin *et al.* teach (column 3, line 65 to column 4, line 36) that for a given luminescent device configuration, the number of curies of gas depends on the gas pressure. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the tritium gas pressure (e.g., 10 to 20 mCi of tritium gas) in the luminescent device of Kessler *et al.*, in order to obtain a desired radiant flux from the luminescent device.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of Linhart *et al.* (US 3,566,125) and Phillips *et al.* (US 2,745,738).

In regard to claim 4 which is dependent on claim 3, the luminescent device of Kessler *et al.* lacks an explicit description that the outer casing is steel. Since Kessler *et al.* do not disclose and/or require a outer casing material, one having ordinary skill in the art at the time of the invention would reasonably interpret the unspecified casing material of Kessler *et al.* as any one of the known conventional casing material that would not require further description. Further, Linhart *et al.* teach (column 3, lines 38-40; column 4, lines 43-45) that an outer casing is advantageously made of a well known metal alloy especially made for the direct fusion of glass to metal. In addition, Phillips *et al.* teach (column 1, lines 48-58) a steel (having the same thermal coefficient of expansion as glass) especially made for the direct fusion of glass to the metal alloy. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a known conventional casing material (e.g., steel having the same thermal coefficient of expansion as glass) as the unspecified outer casing material in the luminescent device of Kessler *et al.*

9. Claims 5, 7, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of Adams *et al.* (US 6,549,279).

In regard to claim 5 which is dependent on claim 3, the luminescent device of Kessler *et al.* lacks an explicit description that the transparent or translucent portion comprises a neutral density filter. However, Kessler *et al.* also disclose (see EPO

automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a neutral density filter as the transparent or translucent portion in the luminescent device of Kessler *et al.*, in order to obtain a second calibration radiant flux from the same luminescent device.

In regard to claim 7 which is dependent on claim 1, the claim limitation "colouring means" is being treated under 35 U.S.C. 112, sixth paragraph and has been construed to cover the corresponding structure described in the specification (e.g., "Coloured filters" in lines 29-31 on pg. 14) and equivalents thereof (MPEP § 2181). The luminescent device of Kessler *et al.* lacks an explicit description that the device further comprises coloring means to alter the color of the light output of the GTLS. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes for several pre-selected wavelengths. Therefore it would have been obvious to one having ordinary skill in the

art at the time of the invention to provide a filter in the luminescent device of Kessler *et al.*, in order to obtain light having a desired wavelength.

In regard to claim **12** which is dependent on claim 1, the luminescent device of Kessler *et al.* lacks an explicit description that said device comprises a filter array. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a filter array for the luminescent device of Kessler *et al.*, in order to obtain a plurality of different calibration radiant fluxes from the same luminescent device.

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of Adams *et al.* (US 6,549,279) and Terashita *et al.* (US 5,073,008).

In regard to claim **6** which is dependent on claim 3, the luminescent device of Kessler *et al.* lacks an explicit description that the transparent or translucent portion is formed from glass or plastic. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach

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(column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. In addition, Terashita *et al.* teach (column 6, lines 65-68) that a neutral density filter comprises a glass plate or a plastic plate.

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a neutral density filter formed from glass or plastic as the transparent or translucent portion in the luminescent device of Kessler *et al.*, in order to obtain a second calibration radiant flux from the same luminescent device.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of Gelman *et al.* (US 5,389,774).

In regard to claim 11 which is dependent on claim 1, the luminescent device of Kessler *et al.* lacks that said device comprises a scalebar graticule. However, Gelman *et al.* teach (Fig. 4) to provide a calibration device comprising a light source (16) and scalebar graticule (15), in order to calibrate an optical measuring system. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a scalebar graticule in the luminescent device of Kessler *et al.*, in order to calibrate an optical measuring system.

12. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of Leveille (US 2002/0096667).

In regard to claims 13 and 15 which are dependent on claim 1, Kessler *et al.* lacks a kit comprising three or more luminescent devices, wherein each of said devices providing a light output of a distinct intensity to the other devices of said kit. However, Leveille teaches (paragraphs 1-9) to provide a calibration light kit, in order to calibrate a

light measuring apparatus. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a plurality of the luminescent devices of Kessler *et al.* having different intensities as a calibration kit.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of Leveille (US 2002/0096667) as applied to claim 13 above, and further in view of Nast (US 4,575,143).

In regard to claim 14 which is dependent on claim 13, the luminescent device of Kessler *et al.* lacks a magnetic handling tool and wherein each of said devices includes a magnetic component. Nast teaches (column 1, lines 51-52) to provide a magnetic handling tool in order to retrieve small objects having a magnetic component from locations that cannot be reached by a mechanical tool. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a magnetic handling tool and the luminescent device of Kessler *et al.* with a magnetic component, in order to retrieve the luminescent devices from locations that cannot be reached by a mechanical tool.

14. Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler *et al.* (DE 38 16 489 A1) in view of Valenta (US 5,321,261).

In regard to claims 16 and 17 which are dependent on claim 1, Kessler *et al.* is applied as in claim 1 above. Kessler *et al.* lacks that the luminescent device is housed in a sample holder of a luminometer. However, Valenta teaches (column 4, line 19 to column 5, line 40) to dispose a plurality of radioluminescent standards in different wells of a microplate, in order to calibrate one or more photomultipliers in a luminometer.

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to place the luminescent device of Kessler *et al.* in a sample holder (e.g., a 6-well plate), in order to calibrate one or more photomultipliers in a luminometer.

In regard to claims **18** and **19** which are dependent on claim 1, Kessler *et al.* in view of Valenta is applied as in claims 16 and 17 above. Kessler *et al.* disclose (see EPO automated translation of column 3, line 35 to column 4, line 12) a method comprising obtaining a reading a sample inserted into the apparatus calibrated using the luminescent device. The method of Kessler *et al.* lacks an explicit description that the sample comprises living cells. However, Valenta teaches (column 1, lines 18-19) to provide a plurality of radioluminescent standards, in order to calibrate one or more photomultipliers in a luminometer used to measure bioluminescent emissions.

Bioluminescence is defined¹ as "the emission of light from living organisms; also : the light so produced". Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention that the method of Kessler *et al.* can be used to measure bioluminescence from living cells.

In regard to claim **20** which is dependent on claim 16, Kessler *et al.* in view of Valenta is applied as in claims 16 and 17 above. Kessler *et al.* disclose (see EPO automated translation of column 3, line 35 to column 4, line 12) a method comprising adjusting the reading of light output of the apparatus to the measured pre-determined intensity of the light output of the luminescent device placed in the apparatus.

¹ Merriam Webster's Collegiate Dictionary 10th Edition

Response to Arguments

15. Applicant's arguments filed 8 August 2007 have been fully considered but they are not persuasive.

Applicant argues that there is no indication or suggestion that the device disclosed in Frank is shaped or sized for housing in a sample holder. Examiner respectfully disagrees. As discussed above, a limitation in a claim to a luminescent device that recited "wherein the device is sized and shaped to be housed in a sample holder" is indefinite because the relationship of parts was not based on any known standard for sizing a luminescent device, but on the dimensions of an unspecified sample holder. Further, Kessler *et al.* disclose (see EPO automated translation of column 2, lines 60-61) an embodiment wherein the GTLS is a 3 mm diameter cylinder with a height of 15 mm. It should be noted that the exemplary GTLS of Kessler *et al.* is of a size and shape to be housed in sample holder (e.g., a commercially available 6-well plate) having optically clear walls for various standard assays with a light measuring apparatus.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The brochure "BD Falcon™ Cell Culture Products" from BD Biosciences, Bedford, MA (no date) provides examples of the sizes and shapes of commercially available sample holders having optically clear walls for various standard assays with a light measuring apparatus.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shun Lee whose telephone number is (571) 272-2439.

The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SL


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